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| SYNGENTA BIOTECHNOLOGY, INC. | | | EXAMINER | |
| PATENT DEPARTMENT | | | FOLEY, SHANON A | |
| 3054 CORNWALLIS ROAD | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | |
|------------------------------|--------------------------------------|--------------------------------------|
| Office Action Summary | Application No. 10/551,894 | Applicant(s) CLOUGH ET AL. |
| | Examiner SHANON A. FOLEY | Art Unit 1619 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on **24 July 2009**.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) **1-20,22 and 24-26** is/are pending in the application.
 4a) Of the above claim(s) **22 and 25** is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) **1-20,22,24 and 26** is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/06)
 Paper No(s)/Mail Date 3/13/06

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on July 24, 2009 is acknowledged. The traversal is on the ground(s) that the instant claims were not found to lack unity in the international application and it appears a contradiction for the US examiner to find a lack of unity. Applicant further supplies an excerpt from 37 CFR § 1.475. Applicant asserts that because both groups share the special technical feature, both groups share unity of invention.

Applicant's traversal has been fully considered, but is found unpersuasive. Contrary to applicant's assertion that the two groups share the corresponding special technical feature, PCT Rule 13 permits unity for the following combination: a product, a first process of making the product and a first method of using the product. Any subsequent method for making and using the product lacks unity of invention with the first group (emphasis added). In the instant case, the first method of using the product claimed is found in instant claim 20. The second method of using the product, i.e. Group II, is found in instant claim 22. Since there are two methods for using the instant product, the second method of use lacks unity of invention with the first group. Therefore, the seeming contradiction of the instant claims for finding lack of unity in two different stages of prosecution is moot since international rules for establishing lack of unity in the instant case is guided by PCT Rule 13.

Applicant also questions that instant claim 26 is found to have unity with both Groups.

A careful review of claim 26 reveals that the claim only depends from claim 1 and not claim 22, as originally supposed. Claim 26's originally grouping within both Groups was erroneous and is now withdrawn from Group II.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-20, 22 and 24-26 are pending, claims 22 and 25 are withdrawn and claims 1-20, 24 and 26 are under consideration.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see paragraph [0025] of the instant published disclosure, USPgPub 2007/0011773. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

Claim 26 is objected to because of the following informalities: "Bacillus thuringiensis" should be italicized. In addition, the claim is drawn to a "method" while being dependent from claim 1, which is drawn to a locus. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites, "the first and second insecticidal toxin has a different mode of action to the second insecticidal toxin." It is not clear what this phrase means. Is the first recitation of "second" in line 2 of the claim redundant? Is the claim intending to state that the first toxin has a different mode of action from the second toxin, or, is the claim intending that the additive mode

of action from the combination of first and second toxins together different from the second? In the interest of compact prosecution, the latter interpretation of the claim (where the first toxin has a different mode of action from the second toxin) will be applied in consideration of the prior art.

Claim 24 recites a trade name of a products and /or specific products sold by specific companies. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 10-12, 15, 16 and 20 rejected under 35 U.S.C. 102(b) as being anticipated by Roush (Phil. Trans. R. Soc. Lond. B. 1998; 353: 1777-1786, provided in the IDS).

Roush anticipates a method of controlling insects by providing a locus in which plant pests feed comprising a first region of plants that express a first insecticidal toxin, but not the

second, and a second region of plants that express a second insecticidal toxin, but not the first. In addition, Roush teaches that the first insecticidal toxin have different binding sites and different modes of action, wherein a pest which develops resistance to the first toxin does not develop resistance to the second toxin. See the last paragraph of sections "(a) Options for two-toxin deployment" beginning in the first column on page 1780 and though section "(d) Effect of Mortality of susceptible homozygotes on pyramids" on page 1781. Roush anticipates that one of the mechanisms for deployment of the toxins is simultaneous distribution within the same field or different fields, i.e. random distribution, see the first paragraph under section "a". Roush also teach providing a region of plants that are non-insecticidal, see section "(c)", bridging pages 1780-1781. In the last paragraph of section "(c)", Roush specifically teaches that cotton plants possess different toxins.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-9 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roush *supra*.

Claims 5-9 require various distances between the first region and the second region, ranging from within a mile to interspersed regions.

Roush teaches that the toxins are deployed simultaneously in different varieties, such as in a seed mix within the same field or neighboring fields, see the first paragraph of section "(a)" on page 1780.

While Roush does not specifically teach seeding of a second region within a mile or adjacent or around the perimeter of the first or alternating strips within the first, these architectural features would have been *prima facie* obvious design alternatives to one of ordinary skill in the art at the time the invention was made since a seed mix within the same field or neighboring fields, as taught by Roush, encompasses various patterns of seed planting.

Instant claims 17-19 require that at each locus comprises at least between 5% to 50% of the two toxins, respectively.

See the teachings of Roush above. While Roush does not specifically teach a percentage of each toxin present at each locus, Roush depicts a refuge area of less than 5% within locuses comprising two-toxin plants, see the lower left side of Figure 2 on page 1780 and the first paragraph under section "(c)". Provided that the two different locuses comprising each toxin are distributed evenly, each locus comprising a single toxin would approach 50%. In addition, Roush also teach that the recommendations in Australia is that at least 20% of cotton and maize should be non-transgenic, see the top of the second column on page 1778 and Figure 2 on page 1780.

One of ordinary skill in the art at the time the invention was made would have been motivated to vary the percentage of toxin present at each of the two locuses with the percentage amount of refugia provided, with a reasonable expectation of success, to delay the onset on insect resistance to the toxins, see section "(c)" and Figure 2. One of ordinary skill in the art at

the time the invention was made would have been further motivated to increase the percentage of refugia provided, thereby decreasing the percentage of the two transgenic locuses, to ensure that a large proportion of pests develops on the non-transgenic refuge hosts, see the top of the second column on page 1778 and Figure 2 on page 1780.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roush as applied to claims 1-12 and 15-20 above, and further in view of Driver et al. (US 5,640,804, cited in the IDS).

See the teachings of Roush et al. At the beginning of section "(a)" on page 1780, Roush teaches that toxins may be deployed individually "in different varieties...as a seed mix". Whether the "different varieties" discussed by Roush is referring to the different toxins or different varieties of plants is unclear. However, it is clear that Roush intends a mixture of different gene expressions in the same field or neighboring fields. Therefore, while Roush does not clearly indicate that the plants expressing the first and second toxins are from different genera, Driver et al. teach different plants planted adjacent to each other, see claims 1, 7, 11 and 13.

One of ordinary skill in the art at the time the invention was made would have been motivated to provide a plant expressing a first toxin with a different genera plant expressing a second toxin to control insect pests, see claim 1 of Driver et al and section "(a)" on page 1780, Roush. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for providing a plant expressing a first toxin with a plant expressing a second toxin to control insect pests, as taught by Roush, of different genera, taught

by Driver et al. since Roush teaches that toxins may be deployed individually "in different varieties...as a seed mix", see section "(a)" on page 1780.

Claims 13 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roush as applied to claims 1-12 and 15-20 above, and further in view of Schnepf et al. (*Microbiology and Molecular Biology Reviews*. 1998; 62 (3): 775-806).

See the teachings of Roush above. Roush does not teach or suggest that the first toxin is a Bt crystal protein of the second toxin is a Bt VIP protein, or vice versa. Roush also does not teach that the first or the second toxin is Bt Cry1Ac.

Schnepf et al. teach that Bt VIP proteins are pesticidal and unrelated to the Cry proteins, see the second full paragraph of the second column on page 776. Regarding Cry1Ac, Schnepf et al. teach that the protein has affinity for aminopeptidase N, see the paragraph bridging pages 783-784.

One of ordinary skill in the art at the time the invention was made would have been motivated to express Bt VIP and Cry1Ac as pesticidal toxins in the pyramided gene expression taught by Roush to delay insect resistance by providing a broad range of toxin divergence, see the first paragraph of section "(b)" on page 1780 of Roush. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for expressing the Bt VIP and Cry1Ac toxins, taught by Schnepf et al., individually, in the method of Roush since Roush specifically teaches that "the two toxins expressed should be as unrelated as possible", see the first paragraph of section "(b)" on page 1780 of Roush.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roush and Schnepf et al. as applied to claims 1-13, 15-20 and 24 above, and further in view of English et al. (US 6,023,013).

See the teachings of Roush and Schnepf et al. above. Neither reference teaches that the first toxin is Bt Cry3A and that the second toxin is Cry3B.

Schnepf et al. also teach Cry3A and Cry1A only show a 36% sequence identity, despite the similarity in 3D structure, see Figure 1 on page 779, the first paragraph under "Toxin Structure" on page 779 and Figure 4 on page 782. In addition, English et al. teach structural differences between the two toxins, see column 87, line 59 to column 88, line 2.

One of ordinary skill in the art at the time the invention was made would have been motivated to express Cry3A and Cry3B as pesticidal toxins in the pyramided gene expression taught by Roush to delay insect resistance by providing a broad range of toxin divergence, see the first paragraph of section "(b)" on page 1780 of Roush and/or to provide an effective insecticide against the Colorado Potato Beetle and the southern corn rootworm, see column 35, lines 39-47 of English et al. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for expressing the Cry3A and Cry3B toxins, taught by Schnepf et al. and English et al., individually, in the method of Roush since Roush specifically teaches that "the two toxins expressed should be as unrelated as possible", see the first paragraph of section "(b)" on page 1780 of Roush and Schnepf et al. and English et al. teach structural divergence between the two toxins.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANON A. FOLEY whose telephone number is (571)272-0898. The examiner can normally be reached on flex, generally M-F 7AM - 3 PM, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyer can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shanon A. Foley/
Primary Examiner
Art Unit 1619